

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Beclazone 50, 100, 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

Beclometasone dipropionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. What Beclazone Easi-Breathe® CFC-Free Inhaler is and what it is used for
2. What you need to know before you use Beclazone Easi-Breathe® CFC-Free Inhaler
3. How to use Beclazone Easi-Breathe® CFC-Free Inhaler
4. Possible side effects
5. How to store Beclazone Easi-Breathe® CFC-Free Inhaler
6. Contents of the pack and other information

1 WHAT BECLAZONE EASI-BREATHE® CFC-FREE INHALER IS AND WHAT IT IS USED FOR

Effect

Beclazone Easi-Breathe® CFC-Free Inhaler contains beclometasone dipropionate, which belongs to a group of medicines called corticosteroids. Beclometasone dipropionate works on your lungs to help prevent asthma attacks by reducing the swelling and irritation in the walls of the small air passages. This eases your breathing problems. Very little corticosteroid gets absorbed into your body. This medicine is not the same type of steroid used by body-builders and athletes to increase their performance.

Usage

Beclazone Easi-Breathe® CFC-Free Inhaler is used to **prevent** asthma in adults, adolescents and children aged 7 to 12 years. This type of medicine is known as a 'preventer'. You must keep on taking this type of medicine regularly, even when you do not seem to have your asthma symptoms.

Do not use Beclazone Easi-Breathe® CFC-Free Inhaler to relieve an asthma attack, wheezing or breathlessness. You will probably need a different kind of medicine in a different coloured pack for this purpose. You may be using an inhaler that widens your airways during an asthma attack. This type of inhaler is known as a 'reliever'. You can safely use your 'reliever' with your Beclazone Easi-Breathe® CFC-Free Inhaler.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE BECLAZONE EASI-BREATHE® CFC-FREE INHALER

Do not use Beclazone Easi-Breathe® CFC-Free Inhaler:

- if you are allergic to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from or have ever suffered from tuberculosis (TB).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Beclazone Easi-Breathe[®] CFC-Free Inhaler.

Contact your doctor if you experience blurred vision or other visual disturbances.

Because your inhaler is used to prevent asthma attacks, it is important to use it regularly, even when you feel well.

It may take a few days for this medicine to work. Do not stop using your inhaler unless you are told to by a doctor.

If you have started to use Beclazone Easi-Breathe[®] CFC-Free Inhaler with, or instead of, taking steroid tablets you should carry a steroid warning card (if you have one) until your doctor tells you that you no longer need to carry it.

Consult a doctor immediately if your usual treatment is not working. Your doctor will tell you if you need any extra treatment. Your dosage should only be increased on medical advice.

Other medicines and Beclazone Easi-Breathe[®] CFC-Free Inhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The following medicines may influence the effect of Beclazone Easi-Breathe[®] CFC-Free Inhaler:

- Other asthma medicines, such as bronchodilators, or other corticosteroids in tablet form.

Some medicines may increase the effects of Beclazone Easi-Breathe[®] CFC-Free Inhaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Beclazone Easi-Breathe[®] CFC-Free Inhaler with food and drink

Beclazone Easi-Breathe[®] CFC-Free Inhaler should be used as prescribed by your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Beclazone Easi-Breathe[®] CFC-Free Inhaler should only be used if recommended by a doctor.

Driving and using machines

Beclazone Easi-Breathe[®] CFC-Free Inhaler does not affect the ability to drive or to use machinery.

3 HOW TO USE BECLAZONE EASI-BREATHE[®] CFC-FREE INHALER

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

All patients are different and your doctor may have prescribed a different dose for you.

The recommended dose for Beclazone Easi-Breathe[®] CFC-Free Inhaler is:

Beclazone 50 micrograms Easi-Breathe[®] CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is sixteen puffs.

Beclazone 100 micrograms Easi-Breathe[®] CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is eight puffs.

Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is four puffs.

Use in children (7-12 years) and adolescents

Beclazone 50 micrograms Easi-Breathe® CFC-Free Inhaler: Take one or two puffs twice daily. Usually the most you would take in 24 hours is four puffs.

Beclazone 100 micrograms Easi-Breathe® CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is two puffs.

Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler is not recommended for use in children.

Hepatic or renal impairment

Dose adjustments are not required. Follow your doctor's instructions.

Instructions for use of the inhaler

Important

Before using your inhaler, please read this leaflet carefully and follow the instructions. If you are not sure how or when to use your inhaler, ask your doctor or a pharmacist.

Do not stop using your inhaler unless your doctor tells you to. If your doctor tells you to stop using your inhaler, take any inhalers you have left back to your pharmacist.

Your Beclazone Easi-Breathe® CFC-Free Inhalers may have been provided with a small spacer device called an Optimiser™. You can use this spacer with your Beclazone Easi-Breathe® Inhaler to reduce some side effects such as sore throat or hoarseness, which are caused when large droplets of the medicine are deposited at the back of your throat. The Optimiser does not significantly affect the amount of medicine reaching your lungs.

Using the Inhaler without the Optimiser (A)

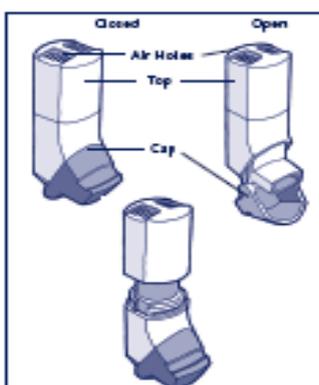
Beclazone Easi-Breathe® CFC-Free Inhalers have been designed to make it easier for you to use. It is a breath-operated inhaler. This means that it only releases a dose when you breathe in.

Important

Before you use your inhaler, please read this leaflet carefully and follow the instructions. Do not rush steps 3 and 4 below. It is important that you start to breathe in as slowly as possible before you start using your inhaler. Practice in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or from the sides of your mouth, you should start again from step 2.

Opening

To open the inhaler, fold down the cap, which fits over the mouthpiece.



Test spray the inhaler before you use it for the first time and also if you have not used the inhaler for five days. To test spray your inhaler, unscrew the top of it so that you can see the metal can inside.

Open the cap, shake the inhaler and spray the aerosol by pressing the can with your finger or thumb.

Close the cap and put the top back on.

1. Before use, shake the inhaler vigorously.



2. Hold the inhaler upright and open it by folding down the cap that fits over the mouthpiece.



3. Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips. Hold the inhaler upright and make sure that your hand is not blocking the airholes. Breathe in slowly and deeply through the mouthpiece. Don't stop breathing when the inhaler puffs the dose into your mouth. Carry on until you have taken a deep breath.



4. Take the inhaler out of your mouth and hold your breath for 10 seconds, or for as long as you comfortably can. Breathe out slowly.



5. After you have used your inhaler, hold it upright and immediately close the cap.
6. If you need to take more than one puff, close the cap, wait at least one minute between doses and then repeat the process from Step 1.

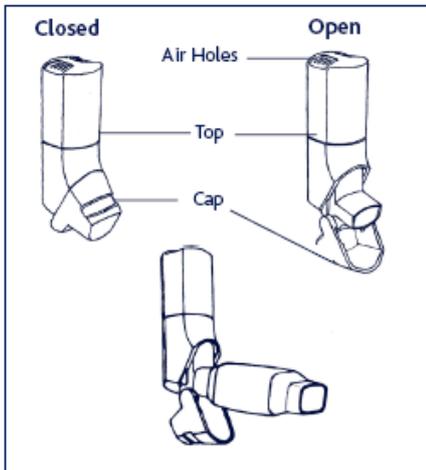
Using the Inhaler with the Optimiser (B)

Beclazone Easi-Breathe[®] CFC-Free Inhalers have been designed to make it easier for you to use. It is a breath-operated inhaler. This means that it only releases a dose when you breathe in.

Important

Do not rush steps 3 and 4 below. It is important that you start to breathe in as slowly as possible just before using your inhaler. Practice in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or from the sides of your mouth, you should start again from step 2. Your doctor or pharmacist

may have already told you to use the Optimiser with your inhaler. If so, follow the instructions in 'How to use your inhaler with the Optimiser (B)' as outlined below. If not, follow the instructions above.

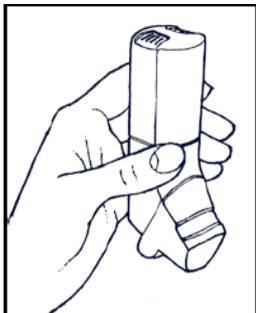


Test spray the inhaler before you use it for the first time and also if you have not used the inhaler for five days. To test spray your inhaler, unscrew the top of it so that you can see the metal can inside.

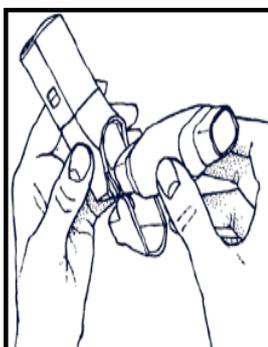
Open the cap, shake the inhaler and spray the aerosol by pressing the can with your finger or thumb.

Close the cap and put the top back on.

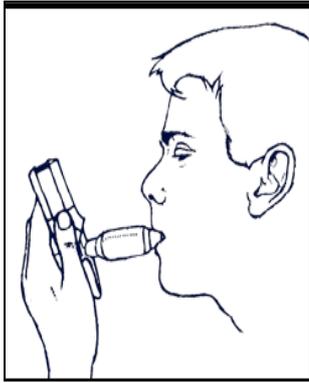
1. Before use, shake the inhaler vigorously.



2. Then hold the inhaler upright and open it by folding down the cap, which fits over the mouthpiece and slot the optimiser firmly onto the mouthpiece of the inhaler.



3. Breathe out normally as far as you comfortably can. Place the mouthpiece of the optimiser between your lips. Hold the inhaler upright and make sure that your hand is not blocking the airholes. Breathe in slowly and deeply through the optimiser. Don't stop breathing when the inhaler puffs the dose into your mouth. Carry on until you have taken a deep breath.



4. Remove the inhaler and optimiser from your mouth and hold your breath for 10 seconds or for as long as you comfortably can.



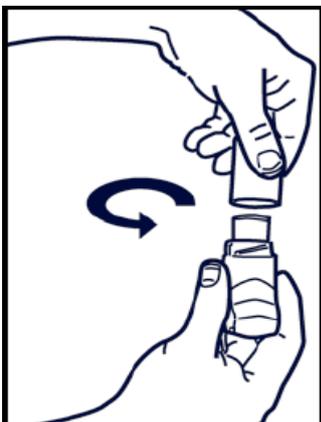
5. After use, hold the inhaler upright, remove the optimiser and close the cap.
6. If you need to take more than one puff, wait at least one minute between doses and repeat from Step 1, above.
7. It is very important to keep the inhaler and optimiser clean, especially in the mouthpiece area to prevent build-up of deposits from the aerosol, washing once a week is recommended.

Cleaning the inhaler

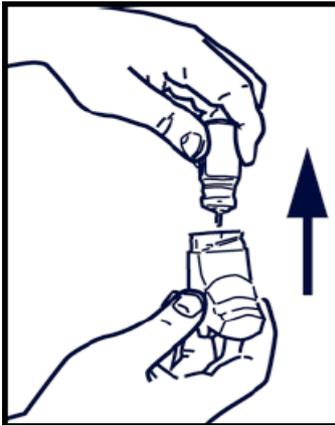
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

CLEAN YOUR INHALER AT LEAST ONCE A WEEK.

- A. Unscrew the top of your inhaler. Keep this top dry at all times.



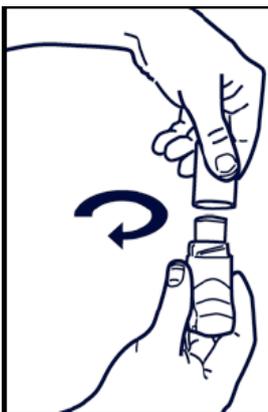
B. Remove the metal can. Do not put the metal can in water.



C. Rinse the inhaler body in warm water and dry it (leave to dry overnight if possible). Do not use very hot water.



D. Put the metal can back in your inhaler and close the cap. Screw the top of your inhaler back onto the body. Do not wash the top part of the inhaler. Do not use any heat to dry the inhaler body.



Failure to allow the mouthpiece to dry properly will result in your inhaler becoming blocked.

What to do if your breathing gets worse

If you notice that you are more short of breath and your wheeze is getting worse, tell your doctor immediately. He or she will tell you if you need any extra treatment.

If you take more Beclazone Easi-Breathe® CFC-Free Inhaler than you should

Your dose has been carefully worked out for you. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you accidentally take more puffs than your doctor has recommended, don't worry. However, if you regularly use more than your recommended dose, you should tell your doctor as soon as possible.

If you forget to take Beclazone Easi-Breathe® CFC-Free Inhaler

Do not take a double dose to make up for a forgotten dose. If you forget to use your inhaler, take your recommended number of puffs when you remember. Then continue your treatment as prescribed by your doctor.

4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience hypersensitivity (allergic) reactions. These include rash, swelling of the face, eyes, lips and throat and wheezing (because of narrowed airways).

Infections and infestations:

Common side effects (may affect up to 1 in 10 people): Candidiasis (thrush) in the mouth and throat, which is seen as white spots. Rinsing your mouth with water immediately after using your inhaler will help prevent this from occurring. If you have these symptoms, tell your doctor but do not stop using your inhaler unless your doctor tells you to.

Immune system disorders:

Rare side effects (may affect up to 1 in 1,000 people): Hypersensitivity reactions as described above.

Respiratory, thoracic and mediastinal disorders:

Common side effects (may affect up to 1 in 10 people): Hoarseness and throat irritation.

Rare side effects (may affect up to 1 in 1,000 people): Wheezing, difficulty in breathing or tightness in your chest. If this happens, stop using your inhaler and tell your doctor immediately.

Skin and subcutaneous tissue disorders:

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Itching, rash and reddening of the skin.

Musculoskeletal and connective tissue disorders:

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Decreased bone density.

Endocrine disorders:

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Decrease in function of the adrenal gland, which is responsible for producing some hormones that control your body.

Eye disorders:

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Cataracts (formation of a film over the eye lens). Glaucoma (a disease in which the eye pressure increases).

Not known side effects (frequency cannot be estimated from the available data): Blurred vision.

Psychiatric disorders:

Not known side effects (frequency cannot be estimated from the available data):

Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.

Additional side effects in children and adolescents

Endocrine disorders:

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Growth retardation in children and adolescents.

Psychiatric disorders:

Not known side effects frequency cannot be estimated from the available data):

Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE BECLAZONE EASI-BREATHE® CFC-FREE INHALER

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze. If your inhaler gets very cold, remove the metal can and warm it in your hands for a few minutes before you use it. Do not warm the can in any other way.

Pressurised aerosol can. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn the can, even if it seems empty.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION**What Beclazone Easi-Breathe® CFC-Free Inhaler contains**

- The active substance is beclometasone dipropionate.
Each puff (metered dose) of Beclazone 50 micrograms Easi-Breathe® CFC-Free Inhaler contains 50 micrograms of beclometasone dipropionate.
Each puff (metered dose) of Beclazone 100 micrograms Easi-Breathe® CFC-Free Inhaler contains 100 micrograms of beclometasone dipropionate.
Each puff (metered dose) of Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler contains 250 micrograms of beclometasone dipropionate.
- The other ingredients are ethanol anhydrous (alcohol) and the propellant norflurane (HFA-134a). This medicine does not contain any CFCs.

What Beclazone Easi-Breathe® CFC-Free Inhaler looks like and contents of pack

- The name of your medicine is
Beclazone 50 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution
Beclazone 100 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution
Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution
- Each pack of Beclazone Easi-Breathe® CFC-Free Inhaler contains a single inhaler that supplies 200 breath-operated doses.

- The pack may also contain a small spacer device called an Optimiser™.
- For inhalation use. Pressurised Inhalation, Solution.

Marketing Authorisation Holder and Manufacturer:

Norton Waterford T/A IVAX Pharmaceuticals Ireland

IDA Industrial Park

Waterford

Ireland

This medicinal product is authorised in the Member States of EEA under the following names:

Belgium: ECOBEC 50 & 250 mcg Easi-Breathe aérosol, oplossing

Ireland: Beclazone 50, 100, 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

This leaflet was last revised in 05/2017.